DEPARTMENT OF MANAGED HEALTH CARE
CALIFORNIA HMO HELP CENTER
DIVISION OF PLAN SURVEYS

FINAL REPORT

FOR A NON-ROUTINE MEDICAL SURVEY

OF

BLUE SHIELD OF CALIFORNIA

A FULL SERVICE HEALTH PLAN

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Final Report of a Non-Routine Medical Survey
Blue Shield of California
A Full Service Health Plan

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EXECUTIVE SUMMARY

Pursuant to Section 1341(a) of the Knox-Keene Act ("Knox-Keene" or the "Act"), the Department of Managed Health Care (the "Department") is charged with executing the laws of California relating to health care service plans and the health care service plan business. Those laws include, but are not limited to, laws that ensure health care service plans provide enrollees with access to quality health care services and protect and promote the interests of the enrollees.

The Department's Division of Plan Surveys conducts medical surveys as a vehicle to ensure health plans meet certain obligations to enrollees under the Act[1]. The Department conducted a routine[2] survey of Blue Shield of California (the "Plan") in January 2006. As a result of a survey finding, the failure to perform timely review of member-initiated quality of care complaints, the Department voiced concern and placed the Plan "on notice" regarding this issue.

The Plan acknowledged the concern and agreed to begin corrective actions immediately. However, in close proximity to the January survey finding, an anonymous Plan employee ("Whistleblower") contacted the Department and reported serious breaches in the Plan's processing of quality of care case reviews.

The "Whistleblower" provided the Department with a list of cases dating back to 2004, alleging the Plan's failure to investigate and process member-initiated complaints. This information superseded the Plan's assurances and, coupled with information derived from members quality of care complaints filed with the Department's HMO Help Center, the Department had reason to conduct a non-routine[3] medical survey of the Plan.

The Division of Plan Surveys notified the Plan in a letter dated June 20, 2006 of its intent to conduct a non-routine medical survey, pursuant to Section 1382(b) and California Code of Regulations Rule 1300.82.1(a). The Department surveyed the Plan and held staff interviews at the Plan's offices in El Dorado Hills, California from June 28 through June 30, 2006 and on July 19, 2006.

The non-routine survey assessed the adequacy of the Plan's process for evaluating and resolving quality of care complaints filed by Plan members. Information and case logs provided by an internal Plan source indicated substantial delay in evaluating and taking appropriate action to

[1] References made throughout this report to "Section ....." are to sections of the Knox-Keene Health Care Service Plan Act of 1975, as amended [California Health and Safety Code Section 1340 *et seq.* ("the Act")]. References to "Rule ....." are to the regulations promulgated pursuant to the Act [Title 28 of the California Code of Regulations].

[2] The Department is required to conduct "routine" medical surveys of licensed managed health care service plans at least every three years. The survey reviews plan operations in relation to access to care, quality improvement, grievances and appeals and utilization management. [Section 1380]

[3] An examination or survey is additional or non-routine for good cause for the purposes of Section 1382(b) when the plan has violated, or the Director has reason to believe that the plan has violated, any of the provisions of Sections 1370. [Rule 1300.82.1(a)(2)]

address quality of care concerns arising from both peer review and the healthcare delivery systems.

The Department reviewed a random selection of member-initiated quality of care files selected from the "Whistleblower" case list. This case list was used by the survey team because it referenced cases dating back to 2004. A routine survey typically draws case samples from the past twelve months. Case review was conducted using a standardized file review survey tool, collecting descriptive data such as type of quality concern, case source, description of alleged problem, key dates, confirmation of quality problem, and level of case severity as defined by the Plan.

The survey tool also evaluated the Plan's performance in the following areas: medical records requests; whether or not the case was reviewed by a clinical professional; whether corrective action was recommended upon confirmation of a quality problem; if corrective actions and results were tracked; if follow-up was conducted with the appropriate provider; and, overall, if the quality issue was handled appropriately.

The Department identified deficiencies related to member-initiated quality of care complaints:

1. The Plan failed to establish procedures in accordance with Department regulations for continuously reviewing member-initiated quality of care complaints, and failed to demonstrate that the Plan's process for conducting review of quality of care concerns was reasonable.

2. The Plan failed to demonstrate that the member-initiated quality of care concerns aspect of the quality program is directed by providers.

3. The Plan failed to provide a quality assurance program designed to ensure member-initiated quality of care problems are identified and corrected for all provider entities.

4. The Plan is deficient in demonstrating Quality Improvement Program requirements in relation to member-initiated quality of care review, including a reasonable methodology for on-going monitoring and evaluation of health services, the scope of the program, and required levels of activity.

5. In relation to member-initiated quality of care complaints, the Plan's quality assurance program is deficient in the level of activity of the program and its effectiveness in identifying and correcting deficiencies in care.

The Plan's legal counsel observed while the Department conducted extensive interviews with Plan operations staff in the Grievance and Appeals Department, Consumer Operations, Quality Management, Network Medical Management, and Quality Improvement and Accreditation. The Department conducted additional interviews with the Plan's Senior Management staff responsible for the operations of key areas referenced above.

The survey team included staff from the Department's Division of Plan Surveys, HMO Help Center, and Office of Enforcement, as well as clinical consultants from the Department's external contractor, Managed Healthcare Unlimited, Inc.

Analysis
These deficiencies pose a serious concern in relation to the Plan's quality program because they reflect an ineffective mechanism to oversee and ensure the quality of services delivered as experienced and reported by Plan members. The scope of a comprehensive quality improvement program may indeed include high scores on nationally-reported score cards; however, of equal, if not greater, importance is the Plan's system to identify, investigate and take appropriate action at the Plan member level. An effective Plan must have both. In addition, using member-initiated complaints as a primary source, the Plan must distinguish between member-reported provider problems and delivery system problems and aggregate information to make changes in either or both systems as appropriate.

A system to detect and resolve member-reported problems is fundamental to a comprehensive and effective quality improvement program. An effective quality improvement program strives to demonstrate high performance on a series of standard measures and has self-policing systems to ensure a quality experience for Plan members in accessing care.

Findings
In accordance with section 1380(g) of the Act, Department analysts shall offer such advice and assistance to the plan as deemed appropriate. This report references such advice and assistance in the form of survey findings. Members of the survey team are in a position to identify weaknesses in Plan operations that have potential to become deficiencies in the future or make suggestions to improve existing processes. Action should be taken as appropriate to benefit the enrollees and the Plan. (See Section II for a Discussion of Findings.)

Conclusion
The Department found the Plan to be in violation of Section 1370 and 1300.70 et al.

Refer to Appendix B for the scope of legal authority and citations used to form the legal basis for this survey.

A COPY OF THIS REPORT HAS BEEN REFERRED TO THE DEPARTMENT'S OFFICE OF ENFORCEMENT.

Survey Results
This Final Report describes five compliance deficiencies. On October 11, 2006, the Plan submitted a corrective action plan, which the Department reviewed and evaluated.

The Department finds that the Plan has initiated remedial action and is on the way to achieving acceptable levels of compliance in several areas; however, the Plan was unable to fully implement and demonstrate the effectiveness of proposed actions within the thirty-day response period.

SECTION I: DISCUSSION OF SURVEY DEFICIENCIES

Table 1 below summarizes survey deficiencies identified during the non-routine survey. All deficiencies cited in this Final Report pertain to the Plan's handling of member-initiated quality of care complaints and require corrective actions by the Plan.

TABLE 1

SUMMARY OF 2006 SURVEY DEFICIENCIES		
#	**DEFICIENCY STATEMENT** [Section or Rule]	
QUALITY MANAGEMENT		
1	**The Plan failed to establish procedures in accordance with Department regulations for continuously reviewing quality of care, performance of medical personnel, utilization of services and facilities, and costs when processing member-initiated quality of care issues. The Plan also failed to demonstrate the reasonableness of procedures and adequacy of the implementation thereof.** [Section 1370 and Rule 1300.70(c)]	**Not Corrected**
2	**The Plan failed to demonstrate that the quality assurance program is directed by providers and that care provided is being reviewed, that problems are being identified, that effective action is taken to improve care where deficiencies are identified, and that follow-up is planned where indicated when handling member-initiated quality of care issues.** [Rule 1300.70(a)(1)]	**Not Corrected**
3	**The Plan failed to provide a quality assurance program designed to ensure member-initiated quality of care problems are identified and corrected for all provider entities, including:** • **Failure to provide administrative and clinical staff support with sufficient knowledge and experience to assist in carrying out their assigned quality assurance activities.** • **Failure to ensure that a level of care which meets professionally recognized standards of practice is being delivered to all enrollees.** [Rule 1300.70(b)(2)(F), Rule 1300.70(b)(1)(A)(B)(C)]	**Not Corrected**

4	**The Plan is deficient in demonstrating Quality Improvement Program requirements in relation to member-initiated quality of care review, including:** • **The methodology for on-going monitoring and evaluation of health services, the scope of the program, and required levels of activity.** [Rule 1300.70(b)(2)(A)]	**Not Corrected**
5	**The Department's assessment of the Plan's member-initiated quality assurance program demonstrates a deficiency in associating the review of quality of care with:** • **The scope of quality assurance activities within the organization; and** • **The structure of the program itself and its relationship to the Plan's administrative structure; and** • **The operation of the quality assurance program; and** • **The level of activity of the program and its effectiveness in identifying and correcting deficiencies in care.** [Rule 1300.70(a)(4)(A)(B)(C)(D)]	**Not Corrected**

The following section describes the conditions and implications of these deficiencies.

QUALITY MANAGEMENT

Deficiencies #1 through #5: See Table 1 above.

TABLE 2: FILE AUDIT RESULTS

FILE TYPE	# OF FILES REVIEWED	ELEMENT	# COMPLIANT	# DEFICIENT
Cases identified by Plan staff as potential quality issues	83*	Reviewed by a quality management clinical professional	18	65
		Reviewed at the appropriate level	16	67
		If quality problem confirmed, appropriate corrective actions and follow-up conducted	0	4
		Overall appropriateness of handling	9	74

*Case files reviewed were open, unresolved, and aged dating back to January 2004.

Case File Review Methodology
The Department requested the Plan provide a sample of quality of care files for survey purposes. The Department based the sampling on a list provided by an internal Plan source, which, in turn, relied on the Plan's grievance database. The case file sample timeframe ranged between September 2004 and April 2006.

Two cases were eliminated from the sample because the Plan had only recently received medical records, and case review was in process. Additional cases were also eliminated as ineligible for the sample (e.g., because they involved only quality of service issues[4]). These actions resulted in a final sample size of 83 files for review. The Department confirmed the majority of cases referred by staff were appropriately identified as situations with a potential quality component and merited investigation by a qualified clinical professional.

The Department requested all related documents with each file, including grievance documents, medical records, evidence of review by any parties, and committee minutes if the case was reviewed by a committee.

[4] A small number of cases appeared to be related solely to quality of service (QOS) (e.g., rude behavior by office staff) rather than quality of care. For purposes of this review, these QOS cases were eliminated from consideration. However, cases that had a QOS component as well as QOC/access aspects were retained in the sample.

The Department's survey team reviewed 83 files using a standardized file review worksheet that collected descriptive data such as:

- Type of quality concern
- Source of case (e.g., grievance, site visit)
- Brief description of the alleged problem
- Key dates (e.g., quality issue identified, medical records/info requested from providers, RN review, physician review, committee review)
- Whether or not the Plan confirmed a quality problem
- Level of severity as defined or coded by the Plan

The worksheet assessed Plan performance against performance measures, including:

- Whether the Plan requested sufficient medical information as background for the case review
- Whether the Plan ensured case review by a quality management clinical professional (RN or MD)
- Whether the Plan ensured case review by the appropriate level of clinical expertise (i.e., RN, MD and/or committee depending upon issues and findings)
- If a problem was confirmed:
  - Whether the Plan took or recommended corrective actions
  - In the event the Plan took corrective action, whether the Plan followed up or tracked the results
  - Whether the Plan conducted follow-up with the involved provider
  - Overall, whether the Plan appropriately handled the case

Case File Conditions:

- In 65 of 83 cases, files showed no evidence of case review by an RN, a physician or other medical professional assigned to quality care review. In 17 of 83 cases, the Plan did not receive medical records/explanations for review. In the remaining 48 cases, the medical records/explanations were received and available for review; however, no review occurred.

- In 17 of 83 cases, providers did not respond to requests for medical records and/or explanations of the case situation. In 8 of 17 cases, there was no evidence that the Plan followed up with the providers (e.g., second requests). In 6 of 17 cases, files evidenced significant delay in follow-up attempts (e.g., 12 months in one case, 10 months in two other cases).

- In 48 of 83 cases in which the Plan had received medical records (i.e., the necessary information was available for review) no review was completed.

Noteworthy timeframes of files pended until review:

- 10 cases waited over one year
- 24 cases waited six months or more
- In 18 cases which were reviewed, six cases showed a three-month delay after receipt of medical records and review of records by the RN. (**Note:** On average, the Department has observed health plans adhering to a 30-day case review standard, once medical records are received.)

- In 4 of 18 cases reviewed by an RN and/or MD, the Plan confirmed a quality of care problem. Based upon the available documentation, the Department was unable to confirm that the Plan had contemplated or took corrective action or performed follow-up for actions taken.

Case Dispositions:

- Records requested November 1, 2005; received March 27, 2006, RN review April 26, 2006. MD review May 31, 2006. No severity level, corrective actions or follow-up were documented.
- Records requested May 11, 2006, RN review May 22, 2006. MD review June 20, 2006. No severity level or corrective actions were documented.
- Records requested September 9, 2005; received September 19, 2005. Case review did not occur until June 2006. Resolution was still in progress at the time of the Department's non-routine survey - the case had been referred for further peer review.
- Records requested September 19, 2005, received September 22, 2005, RN review January 2006. MD review May 2006. No severity level, corrective actions or follow-up were documented.
- 74 of 83 (89%) cases showed some type of problem in the overall handling, i.e., delays, lack of clinical review, absence of corrective action or follow-up.

Plan Organization Conditions:
The Plan presented organization and process overviews. The Department reviewed pre-survey documents from the January 2006 Routine Survey and templates for closing letters to members. The Department interviewed a number of staff and Plan officers and received updates from the Plan since the time of the Non-Routine survey. Plan conditions include:

- During the years 2004 – 2005 to the present, the Plan organization chart reflects the Director, Appeals and Grievance Department; is in charge of the quality of care case handling process. Staff turnover in the Director position occurred in July 2006.

- The quality of care case review process is shared between the Appeals and Grievance Department and the Health Services Department. The Appeals and Grievance Department is responsible for identifying the existence of a quality of care issue, requesting information, and processing a clinical summary ("upstream process"). The

Health Services Department determines the existence and degree of the quality concern, and routes to the appropriate peer review committee for corrective action and follow-up.

- During Plan staff interviews, the Department noted that a physician review process is not part of the "upstream" handling or case flow overseen by the Appeals and Grievance Department. Physician involvement only begins once the file is handed to the physician reviewer.

- A senior Plan official indicated the grievance and appeals process was organized under a single owner. The quality process was separate and apart from this.

- Past the point of record request and/or receipt, in the majority of cases, the review progression stopped at the assignment of an RN's name on the intake sheet; a process within the Appeals and Grievance Department.

- During interviews, Plan staff indicated awareness of a back-log of quality of care cases filed in a file cabinet in the Plan's Woodland Hills office. However, the staff were told to process these cases when they had time.

- During 2004 and 2005, cases were handled by a single RN and a single physician reviewer. Based on a request by the Department, the Plan presented a spreadsheet and pie chart illustrating the "universe" or total number of quality of care cases pending case review from January 2004 – to the present. The total number presented to the Department was 993 cases.

- Statements made by Plan staff suggested the case flow never stopped completely. Because some quality of care cases made it through to the physician review side, staff did not question the process. The proportionally small number of cases in relation to the size of the Plan's enrollment and the large number of contracted providers was never questioned. However, based on the small volume of cases, the Plan reduced resource allocation dedicated to handling quality of care complaints and quality review.

- The Continuous Quality Improvement Committee (CQIC) was responsible for conducting peer review of quality of care cases identified through the Appeals and Grievance Department and screened by the physician reviewer. However, this Committee was disbanded because administration believed the resource allocation was not necessary for so few cases.

- In a majority of cases, a significant time lapse (several months to a year plus) was noted between completion of the nurse review and assignment of a physician name on the case intake sheet. In the majority of files, there was no evidence of completed case review.

- Of the cases completing quality review (suggesting the case was handled by the Appeals and Grievance Department and transferred to physician review for completion of the peer

review process), no case file evidence demonstrated the Plan conducted adequate follow-up of confirmed quality problems.

- On at least three occasions, the Department requested copies of relevant committee minutes to demonstrate the Plan conducted adequate provider follow-up. However, the Plan was unable to produce committee minutes from the CQIC or Board of Directors confirming completion of the quality review process of any files subject to this survey, or summary reports of the quality review process discussed at the Board level.

- The Plan makes great effort to send the standard grievance closing letters to members within the 30-day statutory timeframe. Representations in the closing letter strongly suggest the Plan will conduct investigations and take proper action if warranted. In all cases, the Plan had initiated no investigation at the time the closing letter was sent.

- As evidenced by the file review, no follow-up investigation was undertaken for several months to over a year after the closing letter was sent to the member. Since peer review is considered privileged information, the Plan has no obligation to share results with the member; therefore, the member was placed in a position of reliance on the Plan's representations that it would investigate the concern and take proper action.

- Grievance closing letters state, "Please understand that we judiciously monitor the quality of service and quality of care as an integral part of our operation, and our goal is to promote quality medical care. . . " ". . . we do take member problems seriously; we will be conducting an investigation within the peer review process . . .which remains confidential". In the majority of cases reviewed, the Plan was aware the letters represented to members a judicious and serious investigation, yet the quality program failed to conduct timely investigation and resolution of member quality of care concerns.

Implications: The review of member-initiated quality of care complaints, as part of the overall quality assurance program, must be directed by providers and must document that quality of care provided is reviewed. Problems may arise when an organization has a bifurcated process, in which the physician leadership cannot determine within the organization the ultimate responsibility for the review of quality of care provided to members. The operational component of case identifying and preparation is a critical piece; however, a failure in preliminary processes does not absolve physician responsibility in oversight for all quality of care concerns, both peer review and problems within the health care delivery system.

Physician oversight is the standard. It is the obligation of physicians to identify and investigate whether care provided to members meets professional standards of practice. If not, appropriate corrective actions must be instituted to prevent future occurrences. Failure to address quality issues and to implement appropriate and timely corrective actions jeopardizes the health and welfare of members.

A viable program must include objective evaluations of the effectiveness of all processes within the quality program, such as member-initiated quality of care complaints. The Plan must assess, plan for change, and institute change to continuously improve the quality program. A process step, such as the issuance of closing letters to members and the contents of such letters, should be included in the Plan's self-assessment process and letters revised as appropriate.

To ensure appropriate decision-making, the Plan must utilize qualified individuals who understand the medical aspects of the cases and its legal obligation to ensure quality review procedures are reasonable.

Plan providers must also be held to their contractual responsibilities to provide adequate records for, and participate in, the Plan's potential quality issues investigations in a timely manner. Such participation helps to ensure that the Plan has all the necessary information for decision-making and promotes provider understanding of and adherence to the Plan's care expectations.

Plan's Compliance Efforts:

Deficiency #1: **The Plan failed to establish procedures in accordance with Department regulations for continuously reviewing quality of care, performance of medical personnel, utilization of services and facilities, and costs when processing member-initiated quality of care issues. The Plan also failed to demonstrate the reasonableness of procedures and adequacy of the implementation thereof.** [Section 1370 and Rule 1300.70(c)]

Plan's Compliance Effort: The Plan has initiated a Potential Quality Issue (PQI) redesign project to ensure member-initiated quality of care issues are investigated timely by appropriate Plan staff and review committees end to end. The Plan hired a dedicated Project Manager in May 2006 to manage the process redesign. The redesign project began June 28, 2006 and is expected to continue in 2007. The Plan has implemented the following:

- Organizational changes to handle timely review of member-initiated quality concerns, ensure review by appropriate clinical staff and case referral to proper peer review committees.

- A single database to track cases across multiple departments. The Plan will have the capability to trend PQI's and demonstrate that PQI's are received, investigated by appropriate staff, and resolved timely according to Plan procedures.

Department's Finding Concerning Plan's Compliance Effort:

STATUS: NOT CORRECTED

The Department finds the Plan has initiated remedial action and is on the way to achieving acceptable levels of compliance. The Plan, however, was unable to both implement and demonstrate the effectiveness of proposed actions within the 30-day response period.

The Plan's document submission lacked detail to illustrate how Plan operations, such as appropriate policies, procedures, workflows, and process maps to ensure unity of the process, will change.

As part of the Plan's corrective action plan, the Department directs the Plan to prepare and submit the following documents detailing the changes in Plan operations on a go-forward basis:

- PQI Project Workplan, updated on a monthly basis, and submitted to the Division of Plan Surveys by the 10th calendar day of each month, beginning December 2006 until further notice.
- Updated PQI Process Maps to include turnaround time frames per hand off that occur from Customer Service Departments, Appeals and Grievance Departments, RN review, MD review, Peer review, and Credentialing review. Due to the Department within 30 calendar days.
- Policies and procedures that describe cross functional responsibilities supporting the member-initiated PQI process. Due to the Department within 30 calendar days.
- Revise closing letters providing members information pertaining to the Plan's process of review, and adhere to a reasonable resolution time.

Deficiency #2: **The Plan failed to demonstrate that the quality assurance program is directed by providers and that care provided is being reviewed, that problems are being identified, that effective action is taken to improve care where deficiencies are identified, and that follow-up is planned where indicated when handling member-initiated quality of care issues.** [Rule 1300.70(a)(1)]

Plan's Compliance Effort: The Plan designated a Senior Medical Director responsible for member-initiated quality of care processes, effective July 27, 2006. Responsibilities include:

- Oversight of clinical quality improvement activities.
- Setting overall goals and direction for the Quality Improvement Program.
- Managing resources dedicated to quality improvement.
- Accountability for oversight of the entire PQI process.

The Senior Medical Director delegated responsibility for chairing the Peer Review Committee (PRC) to a Plan Medical Director with support from other Plan medical directors, network physicians, and RN clinical reviewers.

A new physician-driven PRC Charter was initiated in August 2006. The PRC meets monthly and provides a peer review forum to investigate, discuss, and take action on member-initiated

quality of care issues. PRC minutes from August and September 2006 indicate PQI cases were reviewed, severity levels assigned, and further action taken where applicable.

In August 2006 the Plan established and implemented a Severity Policy for gauging the seriousness of quality of care cases and to enable clinical triage of cases based on clinical expertise.

Department's Finding Concerning Plan's Compliance Effort:

STATUS: NOT CORRECTED

The Department finds that the Plan has initiated remedial action and is on the way to achieving acceptable levels of compliance. The Plan, however, was unable to implement and demonstrate the effectiveness of proposed actions within the 30-day response period.

The Department reviewed the PRC minutes for August 2006 which reported case review of 9 member-initiated PQI's. The Plan initiated peer review ranging between 260 days and 576 days from the date of submission of these complaints. The PRC minutes for September 2006 reported case review of 12 member-initiated PQI's. The Plan initiated peer review ranging between 261 days and 551 days from the date of submission of these complaints.

The response lacked detail in describing how the Plan was handling the entire case backlog dating back to 2004 (993 reported cases), beyond the twenty-one cases in a two-month period. The letters sent to providers regarding peer review results continue to cite cases submitted more than a year ago. A significant and continuing backlog precludes the Plan's ability to effectively address and resolve member issues.

The minutes of the August and September meetings, make no mention of the current or on-going PQI inventory, nor any cases resolved within the 90-day turn around time represented by the Plan during the non-routine survey, July- August 2006. The Department is interested in how the Plan is addressing current PQI cases, taking steps to prevent the recurrence of a back-log.

As part of the Plan's corrective action plan, the Department directs the Plan to prepare and submit the following documents on a go forward basis detailing the changes in Plan operations:

- PRC minutes for October and November 2006, due to the Division of Plan Surveys within 30 calendar days. PRC minutes will be treated as "confidential" by the Department.
- PRC minutes beginning with the December 2006 minutes and going forward, due to the Division of Plan Surveys by the 10th calendar day of each month for the previous month's committee meeting. Example: December 2006 meeting minutes will be due to the Division of Plan Surveys by January 10, 2007.
- Updated Peer Review Committee Policy, due to the Division of Plan Surveys within 30 calendar days.

- Updated Credentials Committee Policy, due to the Division of Plan Surveys within 30 calendar days
- Polices and procedures that describe cross functional responsibilities supporting the member-initiated PQI process, including how the quality program is directed by providers and how care is being reviewed, how problems are identified and the actions taken to improve care. Due to the Division of Plan Surveys within 30 calendar days.

Deficiency #3: **The Plan failed to provide a quality assurance program designed to ensure member-initiated quality of care problems are identified and corrected for all provider entities, including:**

- **Failure to provide administrative and clinical staff support with sufficient knowledge and experience to assist in carrying out their assigned quality assurance activities.**
- **Failure to ensure that a level of care which meets professionally recognized standards of practice is being delivered to all enrollees.** [Rule 1300.70(b)(2)(F), Rule 1300.70(b)(1)(A)(B)(C)]

Plan's Compliance Effort: The Plan has implemented the following:

- PQI Case Identification – The Plan has expanded the PQI definition which allows internal departments such as Customer Service, Appeals and Grievances, and Learning, Performance and Quality (training and audit) to utilize a standard definition that describes key categories.
- Customer Service Staff – The Plan has revised workflows with specific system codes for PQI's. Customer Service departments are the primary intake point of contact for member-initiated PQI's.
- Case Preparation – The Plan implemented a Grievance Review Form – a tool for tracking each step of the PQI process, which includes member information, receipt dates, member final letter dates, responsible coordinator activity, medical records request activity, RN/MD clinical review, RN/MD determination, and the assigned severity level.
- Medical Record Pursuit – A new policy describes an escalation process for handling requests for medical records when repeated attempts are not successful. The policy review and approval was scheduled for October 24, 2006.
- Clinical Support – The Plan will increase clinical support staff in the first quarter of 2007.
- Assigning Severity Levels of Care – A new policy, effective August 2006, which provides for clinical review, triage of cases and assignment of severity levels based on clinical expertise.
- Training - The Plan trained staff on process changes in August and September 2006.

Department's Finding Concerning Plan's Compliance Effort:

STATUS: NOT CORRECTED

The Department finds that the Plan has initiated remedial action and is on the way to achieving acceptable levels of compliance. The Plan, however, was unable to fully implement and demonstrate the effectiveness of proposed actions within the 30-day response period.

Going forward, the Department will seek to clarify certain areas of the process re-design. The Plan referenced a new medical record escalation process and the Department is interested in reviewing this policy with the Plan. Also, training for non-clinical staff that has primary "intake" responsibility begins in November 2006. This suggests full implementation of changes may not be realized until after that time.

The Department will confirm the content and completion of training and also whether the Plan has considered conducting cross functional audits in an effort to confirm the effectiveness of these changes.

As part of the Plan's corrective action plan, the Department directs the Plan to prepare and submit the following documents on a go forward basis detailing the changes in Plan operations:

- Customer Service PQI Policy and workflows, due to the Division of Plan Surveys within 30 calendar days.
- Appeals and Grievance PQI Policy and workflows, due to the Division of Plan Surveys within 30 calendar days.
- Quality Management PQI Policy, due to the Division of Plan Surveys within 30 calendar days.
- Medical Records Pursuit Policy, due to the Division of Plan Surveys within 30 calendar days.
- Training Schedule and Outline for non-clinical support staff, due to the Division of Plan Surveys within 30 calendar days.
- PQI cross functional audit policies and procedures, due to the Division of Plan Surveys within 30 calendar days. Note: Cross function includes Customer Service, Appeals and Grievance Department and Quality Management.

Deficiency #4: **The Plan is deficient in demonstrating Quality Improvement Program requirements in relation to member-initiated quality of care review, including:**

- **The methodology for on-going monitoring and evaluation of health services, the scope of the program, and required levels of activity.** [Rule 1300.70(b)(2)(A)]

Plan's Compliance Effort: The Plan has established a 90-day turnaround time for processing member-initiated PQI's. The turnaround time clock begins with data entry and tracks through the Correspondence Unit Tracking (CUT) systems single database as follows:

- Receipt of the PQI complaint
- Acknowledgment

- Closure letter to the member
- Research and investigation
- RN review
- MD review
- PRC review
- Closure letter to the provider against whom the complaint was filed

The Plan will aggressively track performance against the 90-day goal and make additional process and staffing changes to reach the target.

The Plan delivered an analysis of member-initiated quality concerns to the Quality Management Committee and the Board in October 24, 2006 and November 9, 2006. PQI monitoring reports have been incorporated into the annual Quality Improvement Program Evaluation and quarterly audits of random cases for clinical inter-rater reliability will occur to ensure appropriate implementation of the newly established policies.

Department's Finding Concerning Plan's Compliance Effort:

STATUS: NOT CORRECTED

The Plan has initiated remedial actions; however, it has not implemented and demonstrated the effectiveness of these actions within the 30-day response period. The Department is interested in reviewing the Plan's policy and procedure for conducting inter-rater reliability audits and how Quality Management and the PRC will utilize the single database to track and monitor member-initiated PQI's.

As part of the Plan's corrective action plan, the Department directs the Plan to prepare and submit the following documents on a go forward basis detailing the changes in Plan operations:

- PQI CUT System Codes, due to the Division of Plan Surveys within 30 calendar days.
- Clinical Inter-Rater Reliability Policies and Procedures, due to the Division of Plan Surveys within 30 calendar days.
- Report of the 91 PQI cases the Department identified during the non-routine survey in June and July 2006, due to the Division of Plan Surveys within 30 calendar days. Note: The analysis was presented to the Quality Management Committee and CQIC in October and November 2006.
- Detailed status report of the universe of data which included the 921 PQI cases dated 2004 – 2006, due to the Division of Plan Surveys within 30 calendar days. Note: the Department reviewed the data during the on-site survey.
- Monthly PQI Inventory Tracking Reports to include receipt of the PQI, acknowledgment date, medical records request date, member closure letter date, RN research and investigation date, MD review date, Peer Review Committee review date, provider closure letter date, and turnaround time beginning December 2006 and going forward,

due to the Division of Plan Surveys by the 10th calendar day of the month until further notice. (Example: December inventory report submitted to the Department by January 10, 2007).

Deficiency #5: **The Department's assessment of a Plan's member-initiated quality assurance program demonstrates a deficiency in associating the review of quality of care with:**

- **The scope of quality assurance activities within the organization; and**
- **The structure of the program itself and its relationship to the Plan's administrative structure; and**
- **The operation of the quality assurance program; and**
- **The level of activity of the program and its effectiveness in identifying and correcting deficiencies in care.** [Rule 1300.70.(a)(4)(A)(B)(C)(D)]

Plan's Compliance Effort: The Plan has implemented the following:

- The Plan created PQI organizational charts showing current structure and the future structure planned for 2007.

- The October 2006 current organizational structure shows the Senior Medical Director of Quality Management as the PQI process owner, with management service level agreements with the Customer Service and Appeals and Grievance Departments.

- The first quarter 2007 future organizational structure shows the Senior Medical Director with direct responsibility for Quality Improvement and Accreditation, Credentialing, Quality Management, and Peer Review Committee. The structure shows additional positions dedicated to handle PQI's.

Department's Finding Concerning Plan's Compliance Effort:

STATUS: NOT CORRECTED

The Plan has initiated remedial actions in support of achieving acceptable levels of compliance. The Plan, however, has not implemented and demonstrated the effectiveness of proposed actions within the 30-day response period.

The Plan targets 2007 for completion of the process redesign project. The Plan has targeted the first quarter of 2007 to recruit and train approximately twelve new staff members. The Department is interested in reviewing the Plan's new service level agreements between the Senior Medical Director and the operations areas

As part of the Plan's corrective action plan, the Department directs the Plan to prepare and submit the following documents on a go forward basis detailing the changes in Plan operations:

- PQI Project Workplan, updated on a monthly basis, and submitted to the Division of Plan Surveys by the 10th calendar day of each month beginning December 2006 until further notice.
- Revised member-initiated PQI organizational structures submitted to the Division of Plan Surveys by the 10th calendar day of each month beginning in January 2007 until further notice.
- Service Level Agreements definition and description of the specific criteria and requirements for Customer Service and Appeals and Grievance Departments. Description of the actions that will be taken by the PQI Process Owner when Service Level Agreements are not met.

II. DISCUSSION OF FINDINGS

The list below summarizes survey findings identified during the current survey. Survey findings do not rise to the level of an actual deficiency. They are offered to advise and assist the Plan in ongoing improvement efforts. The Department considers it beneficial for the Plan to review, evaluate, and take action as appropriate on findings listed in this Final Report.

QUALITY MANAGEMENT

- The Plan made the following statement to the Department: "After issuing the grievance closing letters to Plan members, there was a breakdown in the process for investigating member-initiated quality concerns." The closing letters state, "Please understand that we judiciously monitor the quality of service and quality of care as an integral part of our operation, and our goal is to promote quality medical care. . . " ". . . we do take member problems seriously; we will be conducting an investigation within the peer review process . . .which remains confidential."

  The Department suggests the Plan evaluate the language in the closing letter to ensure the information is reasonable and correctly reflects the Plan's current efforts in addressing the backlog. Going forward, letters should account for and inform members of the Plan's reasonable time frame for resolution.

- Investigations into delivery system problems may not involve physician peer review and, therefore, confidentiality is not required. The Department suggests the Plan create a member letter that describes the Plan's process for investigating and resolving the member's specific issue.

The Department strongly recommends, when possible, the Plan separate system problem investigation from peer review and inform the member of the steps the Plan took to resolve the issue. This will support greater Plan accountability to its members.

SECTION III: SURVEY CONCLUSION

The Department will conduct follow-up through close monitoring and review of requested documents. The Plan has demonstrated considerable effort to correct these deficiencies; therefore, the Department will issue a follow-up report, confirming full compliance, within six to eight months.

A P P E N D I X A

A. OVERVIEW OF PLAN OPERATIONS

The table below summarizes the information submitted to the Department by the Plan during the routine survey January 2006.

PLAN PROFILE

Type of Plan	Full Service, Mixed Model, Not for Profit HMO, Point of Service, PPO		
Service Area(s) *(Counties, in full or in parts)*			
HMO/Point of Service	Alameda Butte Contra Costa El Dorado Fresno Kern Kings Los Angeles Madera Marin Mariposa	Mendocino Merced Nevada Orange Placer Riverside Sacramento San Bernardino San Diego San Francisco San Joaquin	San Luis Obispo San Mateo Santa Barbara Santa Clara Santa Cruz Solano Sonoma Stanislaus Tulare Ventura Yolo

PPO	Alameda Alpine Amador Butte Calaveras Colusa Contra Costa Del Norte El Dorado Fresno Glenn Humboldt Imperial Inyo Kern Kings Lake Lassen Los Angeles	Madera Marin Mariposa Mendocino Merced Modoc Monterey Napa Nevada Orange Placer Plumas Riverside Sacramento San Benito San Bernardino San Diego San Francisco San Joaquin	San Luis Obispo San Mateo Santa Barbara Santa Clara Santa Cruz Shasta Sierra Siskiyou Solano Sonoma Stanislaus Sutter Tehama Trinity Tulare Tuolumne Ventura Yolo Yuba

Number of Providers	**Primary Care**	**Specialty Care**	**Affiliated Medical Groups or IPAs**
	19,713	29,968	250

Number of Members as of 11/30/2005	**Product Lines**	**Members**
	Group HMO/Point of Service	1,204,155
	Individual HMO	25,716
	Group PPO	684,996
	Individual PPO	265,513
	Healthy Family HMO	35,456
	Healthy Family PPO	5,727
	Total	**2,221,563**

A P P E N D I X B

B. APPLICABLE STATUTES AND REGULATIONS

The following are the specific citations used in this routine medical survey Preliminary Report in identifying the deficiencies.

QUALITY OF CARE

Deficiency #1: **The Plan failed to establish procedures in accordance with Department regulations for continuously reviewing quality of care, performance of medical personnel, utilization of services and facilities, and costs when processing member-initiated quality of care issues. The Plan also failed to demonstrate the reasonableness of procedures and adequacy of the implementation thereof.**

Citations:

Section 1370

Every plan shall establish procedures in accordance with department regulations for continuously reviewing the quality of care, performance, or medical personnel, utilization of services and facilities, and costs. Notwithstanding any other provision of law, there shall be no monetary liability on the part of, and no cause of action for damages shall arise against, any person who participates in plan or provider quality of care or utilization reviews by peer review committees which are composed chiefly of physicians and surgeons or dentists, psychologists, or optometrists, or any of the above, for any act performed during the reviews if the person acts without malice, has made a reasonable effort to obtain the facts of the matter, and believes that the action taken is warranted by the facts, and neither the proceedings nor the records of the reviews shall be subject to discovery, nor shall any person in attendance at the reviews be required to testify as to what transpired thereat. Disclosure of the proceedings or records to the governing body of a plan or to any person or entity designated by the plan to review activities of the plan or provider committees shall not alter the status of the records or of the proceedings as privileged communications.

Rule 1300.70(c)

In addition to the internal quality of care review system, a plan shall design and implement reasonable procedures for continuously reviewing the performance of health care personnel, and the utilization of services and facilities, and cost. The reasonableness of the procedures and the adequacy of the implementation thereof shall be demonstrated to the Department.

Deficiency #2: **The Plan failed to demonstrate that the quality assurance program is directed by providers and that care provided is being reviewed, that problems are being identified, that effective action is taken to improve care where deficiencies are identified, and that follow-up is planned where indicated when handling member-initiated quality of care issues.**

Citation:

Rule 1300.70(a)(1)

The Quality Assurance program must be directed by providers and must document that the quality of care provided is being reviewed, that problems are being identified, that effective action is taken to improve care where deficiencies are identified, and that follow-up is planned where indicated.

Deficiency #3: **The Plan failed to provide a quality assurance program designed to ensure member-initiated quality of care problems are identified and corrected for all provider entities, including:**

- **Failure to provide administrative and clinical staff support with sufficient knowledge and experience to assist in carrying out their assigned quality assurance activities.**
- **Failure to ensure that a level of care which meets professionally recognized standards of practice is being delivered to all enrollees.**

Citations:

Rule 1300.70(b)(2)(F)

There must be administrative and clinical staff support with sufficient knowledge and experience to assist in carrying out their assigned QA activities for the plan and delegated entities.

Rule 1300.70(b)(1)(A)(B)(C)

To meet the requirements of the Act which require plans to continuously review the quality of care provided, each plan's quality assurance program shall be designed to ensure that: A level of care which meets professionally recognized standards of practice is being delivered to all enrollees, quality of care problems are identified and corrected for all provider entities, and physicians (or in the case of specialized plans, dentists, optometrists, psychologists or other appropriate licensed professionals) who provide care to the plan's enrollees are an integral part of the Quality Assurance program.

Deficiency #4: **The Plan is deficient in demonstrating Quality Improvement Program requirements in relation to quality of care review, including:**

- **The methodology for on-going monitoring and evaluation of health services, the scope of the program, and required levels of activity.**

Citation:
Rule 1300.70(b)(2)(A)
There must be a written Quality Assurance plan describing the goals and objectives of the program and organization arrangements, including staffing, the methodology for on-going monitoring and evaluation of health services, the scope of the program, and required levels of activity.

Deficiency #5: **The Department's assessment of a Plan's quality assurance program demonstrates a deficiency in associating the review of quality of care with:**

- **The scope of quality assurance activities within the organization; and**
- **The structure of the program itself and its relationship to the Plan's administrative structure; and**
- **The operation of the quality assurance program; and**
- **The level of activity of the program and its effectiveness in identifying and correcting deficiencies in care.**

Citation:
Rule 1300.70(a)(4)(A)(B)(C)(D)
The Department's assessment of a plan's Quality Assurance program will focus on the scope of Quality Assurance activities within the organization, the structure of the program and its relationship to the plan's administrative structure, the operation of the Quality Assurance program, and the level of activity of the program and its effectiveness in identifying and correcting deficiencies in care.

PLAN APPENDED STATEMENT

The Plan has appended its response to this Report as authorized under section 1382(d) of the Act. To view that appended plan response, please access the link below:

Final Report Blue Shield of California Quality of Care Non-routine Survey